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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,463	10/30/2003	Kevin S. Marchitto	D6323D	7989

7590 02/07/2007
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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/697,463

Applicant(s)

MARCHITTO ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

The remarks and amendment filed 10/16/06 are acknowledged.

Claims 1 and 5-11 are pending. Claims 7 and 8 stand withdrawn.

Claim 1, 5, 6 and 9-11 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

The oath filed 10/30/03 is acceptable.

Terminal Disclaimer

The terminal disclaimer filed on 10/16/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/739,680 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

Claim 1 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 45 of copending Application No. 10/774,320.

Applicant argues that the composition of claim 1 of '320 which is required by claim 45 owing to the dependency of the claims, requires a biomolecule(s) and an electromagnetic energy absorbing species associated therewith. Applicant asserts that these elements are patentably distinct and not encompassed by instant claim 1 which is now drawn to a method of enhancing an ELISA reaction. Applicant argues that only ELISA reactant and medium are placed in the reaction Bessel and are not associated with any additional EM-absorbing species or a substance not present with an ELISA assay.

Applicant's argument is unpersuasive. Claim 1 of '320 requires at least a biomolecule and an EM-absorbing specie. Instant claim 1 has open language ("comprising") and can include other elements. The biomolecule and EM-absorbing specie of claim 1 can be viewed as additional elements or one can consider tht the enzyme associated with the ELISA reaction system is a biomolecule that absorbs EM.

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Another alternative is that the EM-absorbing specie of '320 meets the limitation of the reactants of instant claim 1 because the reactants of instant claim 1 must absorb energy to increase their energy state.

Response to Arguments

Applicant's arguments regarding the prior art rejection in the last Office action have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

Claims 1, 5, 6 and 9-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bystryak et al. (US 5,776,703) in light of Morton et al. (1934; abstract only).

Bystryak discloses a method to photochemically amplify horseradish peroxidase-mediated immunosorbent assays (ELISA). The method comprises a dark reaction wherein a first antibody (A1) having an affinity for an analyte, such as an antigen (An) is bound to a solid support; the bound A1 is contacted with a material suspected of having An to form a complex A1-An. The complex is then reacted with an enzyme-tagged antibody (EA2), wherein the second antibody also has affinity for An, to form a second complex: EA2-A1-An. The enzyme can be horseradish peroxidase. The second complex is reacted with o-phenylenediamine (o-PD) and hydrogen peroxide so that o-PD is converted to 2,3-diaminophenazine (DAP). The amount of DAP that is generated by the enzyme-mediated oxidation of o-PD is proportional to the EA2-A1-An complex, which is a measure of the analyte in the sample.

This disclosure meets the limitations of claim 1 wherein the reactants (o-PD, hydrogen peroxide, etc.) and the means for ELISA (antibodies, etc.) are combined in a reaction vessel. The sensitivity of the dark reaction is increased by placing the dark reaction mixture in a vessel having an irradiation means and then irradiated from about 400 to 500 nm, thereby initiating further production of DAP, thereby enhancing the optical density signal measured by the spectrophotometer (claim 1, col. 2, lines 18-55). The disclosure of radiation having a wavelength of 400 to 500 nm meets the limitations of instant claims 5

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and 6. This disclosure meets the limitations of instant claim 1 wherein energy is applied to one or more of the reactants which results in an increase in the amount of DAP. Bystryak teaches that the reactants are photosensitive owing to their quantum chemical structure and properties (col.2, lines 9-18). The light photons serve as a catalyst by increasing and excited energy state of o-PD to form more DAP (col. 2, lines 45-47 and col. 4, lines 5-7).

Bystryak is silent regarding the alteration of the molecular state of the reactants upon irradiation. However, Morton discloses that benzene and its derivatives, including o-PD, absorb energy in the range of 260-405 nm and that the absorption of this energy corresponds with changes in vibrational sub-levels. Thus, the method of Bystryak practices the same physical steps as-claimed: reactants and a medium for ELISA are placed in a reaction vessel having an irradiation means. The reactants are irradiated, they absorb energy and achieve an increased energy state thereby increasing the rate of formation of the product of the ELISA reaction. The irradiation of the substrate, o-PD, inherently results in an alternation of its vibrational state, as in instant claims 9-10. As noted *supra*, Bystryak teaches that the irradiation of o-PD increases its excited state energy and that the light photons act as a catalyst. Thus, the transition state of the reactant is altered, as in instant claim 11.

The disclosure by Morton is a supporting reference and properly used in a rejection under of U.S.C. 102 since it describes the inherent effect of UV radiation on the vibrational state of o-DP. MPEP 2131.01.

No claim is allowed.

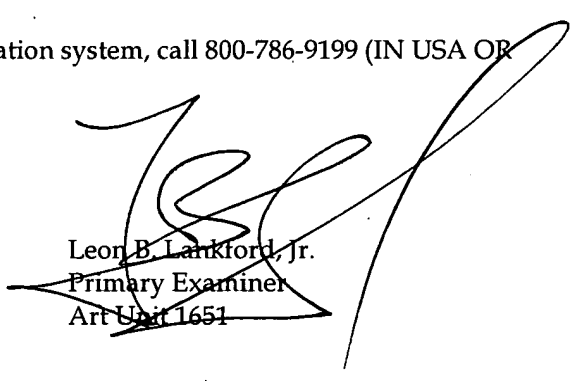
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
AU 1651



Leon B. Lankford, Jr.
Primary Examiner
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